

Nuclear Regulatory Commission

§ 35.3045

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include—

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

(b) The record must contain—

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Subpart M—Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or

radiation from byproduct material results in—

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.